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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,502	03/19/2004	Mary L. Cunningham	04289-00190-US	7682

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EXAMINER

KHARE, DEVESH

ART UNIT PAPER NUMBER

1623

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/804,502	Applicant(s) CUNNINGHAM ET AL.	
	Examiner Devesh Khare	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/30/2004</u> . | 6) <input type="checkbox"/> Other: ____.  |

This application claims benefit of 60/456,163 filed 03/20/2003.

An action on the merits of claims 1 and 2 is contained herein below.

**Objection**

Claims 1 and 2 are objected to because of the following informalities:

In claims 1 and 2, the abbreviations "HP 3" and "HP 4+" should be preceded in their first occurrence by the specific identity of the entities said abbreviations are intended to represent in the claims. Thereafter, the use of the abbreviation in the claims will be favorably considered and explicitly understood.

Appropriate correction is required.

***Specification***

(1) The specification is objected to as failing to provide reference to the priority of the provisional application serial no. 60/456,163, filed 03/20/2003.

(2) The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 1 contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrase "32 to 38% by weight water" in claim 1 does not have adequate support in the specification. The specification on page 5, discloses the % weight of the total solids in the maltitol solution and the solvent for the maltitol solution is water.

**35 U.S.C. 112, second paragraph rejection**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under the second paragraph of 35 U.S.C. 112, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

(1) Claims 1 and 2 recite, the phrase "HP 3 compounds and HP 4+ compounds", it is unclear what is the identity in terms of a name or formula for the "compounds". In absence of such name or formula, claim, which does not depict it, is indefinite.

(2). Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: In the hydrogenation reaction of step (a) wherein a feedstock comprising maltose and glucose is subjected to a hydrogenation in the presence of a hydrogenation catalyst and a promoter; the reaction fails to identify the solvent critical to the reaction.

(3) In claim 2, step (b), it is unclear what is the identity in terms of a name or formula for the phrase "ion-exchange" in the ion-exchange step. It is unclear whether the ion exchange step uses the anion or cation or both resins.

(4) In claim 2, step (a), it is unclear what is the identity in terms of a name or formula for the phrase "hydrogenation catalyst". In absence of such name or formula, claim, which does not depict it, is indefinite. It is noted that the specification on page 9 discloses the

raney nickel catalysts including preferred catalyst molybdenum promoted raney nickel catalyst. It is unclear whether the phrase "hydrogenation catalysts" includes catalysts other than raney nickel catalyst.

**35 U.S.C. 103(a) rejection**

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.*

**Claim 1** is rejected under 35 U.S.C. 103(a) as being unpatentable over Lynch (U.S. Patent 4,471,001).

Lynch teaches the hydrogenated maltose solution containing maltitol, sorbitol and minor amounts of higher saccharides and a process thereof, useful in formulating confections and food decorating specialties (abstract). Lynch discloses that aqueous maltitol syrups can contain 60-85% by weight solids (col.3, line 55). Lynch does not disclose specifically the water content in said aqueous maltitol solution, however Lynch discloses the solid content of 60-85% by weight in aqueous maltitol solution therefore one skilled in the art would assume the water content in the range of 15-40% by weight in the maltitol solution which renders the instantly claimed 32-38% water content obvious. Furthermore, Lynch discloses that maltitol syrup obtained from the hydrogenated maltose solution on a dry weight basis can have 25-94% maltitol, 2-30% sorbitol and

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0.05-2% reducing sugars and higher saccharides on a dry weight basis (col.3, lines 55-59). It is noted that HP 3 and HP 4+ are defined as hydrogenated tri- and quat- and greater saccharides of reducing sugars (specification page 2, 3<sup>rd</sup> para.) therefore prior art's 25-94% maltitol, 2-30% sorbitol and 0.05-2% reducing sugars and higher saccharides on a dry weight basis render the maltitol solution of instant claim prima facie obvious.

Therefore, one of ordinary skill in the art would have found the applicants claimed maltitol solution; to have been obvious at the time the invention was made having the above cited reference before him. Since Lynch discloses the hydrogenated maltose solution containing maltitol, sorbitol and minor amounts of higher saccharides, one skilled in the art would have a reasonable expectation for success in following the teachings of Lynch to accomplish a maltitol solution of claim 1 by varying the amounts of solids to water contents and comprising each of maltitol, sorbitol, HP3 and HP4+ in a concentration to prevent maltitol from crystallizing out of solution. The motivation for doing so is provided by Lynch reference which discloses that "maltitol syrups are surprisingly resistant to the proliferation of airborne microorganisms such as mold when the total solids content is about 75% by weight and preferably about 80% (col. 1, lines 47-51) and the non-crystallizing maltitol solution is useful in cosmetic, pharmaceutical, confectionary and food preparations in the form of a clear transparent non-crystallizing gels (col.1, lines 60-65).

**Claim 2** is rejected under 35 U.S.C. 103(a) as being unpatentable over Lynch (U.S. Patent 4,471,001) in view of Darsow (U.S. Patent 5,641,872).

Lynch teaches the hydrogenation of maltose to produce a solution comprising maltitol and higher saccharides, useful in formulating confections and food decorating specialities (abstract). Lynch discloses the hydrogenation of aqueous corn syrup containing maltose, glucose and higher saccharides in the presence of nickel catalyst at 160° C at a pressure of hydrogen at 1500-2000 psi (col.2, lines 40-58). Lynch also discloses purification of said hydrogenated mixture through a cationic exchange and anionic exchange resin and thereafter concentration to remove water (col.2, lines 59-62). It is noted that HP 3 and HP 4+ are defined as hydrogenated tri- and quat- and greater saccharides of reducing sugars (specification page 2, 3<sup>rd</sup> para.) therefore prior art's hydrogenated mixture comprising maltitol, sorbitol and reducing sugars and higher saccharides on a dry weight basis (col.3, lines 55-59) render the maltitol solution obtained from the hydrogenation of maltose and glucose of instant claim obvious.

Lynch differs from the applicant's invention in that Lynch does not provide the use of a reaction promoter comprising magnesium powder in a hydrogenation reaction of maltose and glucose to produce a solution comprising maltitol.

Darsow teaches the use of non-catalytic pyrophoric metal powders such as aluminium, manganese or titanium in combination with the hydrogenation nickel catalyst in the hydrogenation reaction of maltose to produce epimer free maltitol (col.3, lines 50-65). Therefore one skilled in this art would be motivated to substitute the aluminium powder (pyrophoric metal powder) of said prior art with the non-catalytic pyrophoric

metal powder of magnesium because the use of magnesium may also be helpful in the higher hydrogenation activity due to its reducing properties which renders the instantly claimed use of pyrophoric magnesium powder obvious. Darsow also discloses the use of the catalyst powder containing Ni/Mo/Al wherein the Al content is 6.1% (col.11, example 10).

Therefore, one of ordinary skill in the art would have found the applicants claimed method of making maltitol solution by subjecting a feedstock comprising maltose and glucose to a hydrogenation reaction in the presence of a hydrogenation catalyst and a reaction promoter comprising magnesium powder, to have been obvious at the time the invention was made having the above-cited references before him. Since Lynch teaches the hydrogenation of aqueous corn syrup containing maltose, glucose and higher saccharides in the presence of nickel catalyst and the use of an ion-exchange in the purification and Darsow overcomes the deficiency of Lynch reference by disclosing a the use of non-catalytic pyrophoric metal powders in combination with the hydrogenation nickel catalyst in the hydrogenation reaction of maltose to produce epimer free maltitol, one skilled in the art would have a reasonable expectation for success in combining both references to obtain a maltitol solution which is epimer free. Lynch provides the motivation to use the above-described process to prepare novel maltitol/sorbitol containing syrups useful in the manufacture of clear gels, which can be, used in cosmetic, pharmaceutical, confectionary and food preparations (col.3, lines 35-50).



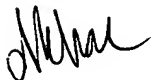
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Any inquiry concerning this communication or earlier communications from the

Examiner should be directed to Devesh Khare whose telephone number is (571)272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang, Supervisory Patent Examiner, Art Unit 1623 can be reached at (571)272-0627. The official fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Devesh Khare, Ph.D., J.D.  
Art Unit 1623  
June 26, 2006